HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 28, 1999

WARNING LETTER
CIN-WL-99-220

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Glenn Fischer, President
BOC Group, Inc.
575 Mountain Avenue
Murray Hill, NJ 07974

Dear Mr. Fisher:

On February 16, 17, March 30 and April 1, 1999, the Food and Drug Administration conducted an inspection of your Oxygen U.S.P. air liquefaction plant at 6744 County Road 10, Delta, Ohio 43515.

Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product, Oxygen U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations documented during the inspection included:

A) Failure to validate the air separation process.
B) Failure to validate the computer system controlling the air separation process.
C) Failure to calibrate the [redacted] oxygen analyzer on one of [redacted] tank truck loads.
D) Five of the [redacted] tank truckloads that were tested, released and distributed were based upon test results of the [redacted] oxygen analyzer calibrated by an employee whose training in calibration was not recorded.
E) All tank truckloads of Liquid Oxygen USP were distributed prior to supervisory (quality unit) review and release.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

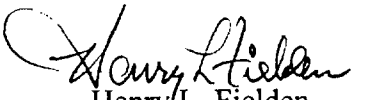
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office with fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent

the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,



Henry L. Fielden
District Director

cc: Philip E. Taylor, Plant Manager
BOC Group Inc.
405 E. Zeller Road
Fostoria, Ohio 44830